

**K201206 Pivot Breath Sensor**Jun 30, 2021  
422 days to decisionK201206 · Product code: **CCJ** · Toxicology  
Source: <https://www.510kdatabase.net/k201206/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Analyzer, Gas, Carbon-monoxide, Gaseous-phase (CCJ) |
| Date received         | May 4, 2020   |
| Decision date         | Jun 30, 2021  |
| Days to decision      | 422 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Carrot, Inc.</b>                   |
| Location       | Redwood City, CA, US                  |
| Contact        | Sara Lippert                          |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------|
| Consulting firm | <b>Hogan Lovells US LLP</b> |
| Contact         | Jonathan S. Kahan           |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**CLINICAL EVIDENCE - NCT04133064**

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**Assessment of the Pivot Breath Sensor: Single-Arm Cohort Study**

|                   |   |
|-------------------|---|
| Status            | Completed   |
| Enrollment        | 234 patients (actual)   |
| Study sites       | 1 site  |
| Condition studied | Smoking Reduction; Smoking Behaviors; Smoking, Tobacco; Smoking Cessation |
| Primary purpose   | Other   |
| Study type        | Interventional  |
| Study design      | Single group  |
| Masking           | Open label  |
| Completion date   | Oct 1, 2020   |
| Sponsor           | Jennifer Marler, MD (Industry)  |

**Primary outcome**

Number of Participants With Different Stages of Change in Desire to Quit Smoking

**Secondary outcome**

Feedback on Breath Sensor Setup, Experience and Use

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04133064](https://clinicaltrials.gov/study/NCT04133064)